· Applicant:

Heath, et al.

Filed: Title: July 27, 1999

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REMARKS

Applicant further affirms the election made January 4, 2001, canceling claims 20-22. Applicant reserves the right to file the remaining claims in a divisional application at a later date. By this amendment, Applicant has amended claims 1, 6, 9, and 14, having amended claims 6 and 14 in part by incorporating the subject matter of claims 7 and 15 respectively. Claims 7 and 15 have been canceled. Claims 1-6, 8-14, and 16-19 remain pending.

Double Patenting Rejection

The Examiner provisionally rejected claims 6, 8, 14 and 16-19 under the judicially created doctrine of obviousness-type double patenting over claims 8-9, 23-25, 30-31 and 34-40 of copending U. S. Patent Application Serial No. 09/255,146. Should the claims asserted in the rejection issue, Applicant will review such claims, and if appropriate, file a terminal disclaimer. However, since the claims have not issued, and it is unknown what the claims will recite when they do issue, Applicant submits that no action is currently necessary with respect to this rejection.

Claim Rejections Under 35 U.S.C. § 112

Claims 1-5, 7, 9-13 and 15 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention.

While Applicant disagrees strongly with the Office Action, Applicant has amended the claims to remove the references to which the Office Action claims are new matter. Applicant has thoroughly presented the extensive support for the amendments in numerous responses, and believes that full support exists for the changes, but for the sake of brevity will not repeat the arguments herein. They are however, incorporated by reference in their entireties. In reviewing the rejections and the cited art, Applicant has determined that the changes are not

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necessary to distinguish over the cited art. As such, Applicant has amended the claims to remove the alleged new matter.

Claim Rejections Under 35 U.S.C. § 102

Claims 6, 8, 14 and 16-18 were rejected under 35 U.S.C. §102(b) as being anticipated by Petschek et al. (U.S. Patent 5,389,339). Applicant has amended claims 6 and 14 to clearly define over Petschek et al. Specifically, the claims have been amended to recite that the process of the claims occurs outside of the centrifuge, with the exception of the centrifugation processes. This is clearly different from Petschek et al. which performs its process steps within the centrifuge. See Petschek et al., including claims 1 and 43, and the specification at many places where all functions of the processes of Petschek et al. are performed within the rotor. Pipette tips are used to dispense reagents into the tubes contained in the rotor, and all functions of the operation of Petschek et al. are contained within the rotor. For example only, and not by way of limitation, Petschek et al. includes the following:

- 1. Figure 1B shows an assembly with no arms or robot-type motion mechanics; Col. 5, ll. 15-20 describe figure 1B (bottles on one side of the cabinet and feed to samples in the rotor);
- 2. Col. 2, Il. 38-41 (dispensing is affixed to rotor);
- 3. Col. 3 ll. 3-5 (mixing performed by agitating rotor);
- 4. Col. 3 ll. 22-25 (delivery conduit leads to centrifuge);
- 5. Col. 5 ll. 4-5 ("addition of one or more reagents to the sample tubes in rotor");
- 6. Col. 5 ll. 30-31 (position of the pipette in relation to the rotor);
- 7. Col. 5 l. 65 - col. 6 l. 5 (describes the arrangement of the rotor to the rack, to maintain the pipette tip-to-sample relationship when the centrifuge is indexed); and
- 8. Col. 10 describes the protocol commands of Figs. 4 and 5, and at 11. 54-55 recites "command steps are performed for each cell sample tube in the centrifuge rotor."

Support for the present claimed process functions occurring outside the centrifuge appears in numerous places throughout the original specification and claims, including, for example, original Figure 2; page 5, Il. 17-19 and Il. 25-27; page 6, Il. 3-4; page 10, Il. 9-13; Applicant: Filed:

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and page 13, ll. 3-11; all of which indicate processes performed outside of a centrifuge. Claims 6, 8, 14, and 16-18 are therefore believed to be allowable.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-9, 10, 14-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464). Claims 1, 6, 9, and 14 have been amended as has been discussed above. Claims 7 and 15 have been canceled. Lange et al., in combination with Petschek et al. does not teach or suggest the claimed subject matter, and as such, claims 1-6, 8-10, 14, and 16-18 are believed to be allowable.

Claims 9, 11 and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464) and further in view of Johnson et al. (U.S. Patent 5,584,039). Claim 9 has been amended as has been discussed above. Johnson et al. and Lange et al., alone or in combination with Petschek et al. do not teach or suggest the claimed subject matter, and as such, claims 9, 11, and 19 are believed to be allowable. Claim 11 depends from and further defines patentably distinct claim 9 and is also believed allowable. Claim 13 depends from and further defines patentably distinct claim 14 and is also believed allowable.

Claims 9 and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464) and further in view of Poulter et al. (U.S. Patent 6,072,795). Claim 9 has been amended as has been discussed above. Poulter et al. and Lange et al., alone or in combination with Petschek et al. do not teach or suggest the claimed subject matter, and as such, claims 9 and 12 are believed to be allowable. Claim 12 depends from and further defines patentably distinct claim 9 and is also believed allowable.

Claims 9 and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464) and further in view of McNutt (U.S. Patent 5,802,389). Claim 9 has been amended as has been

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discussed above. McNutt et al. and Lange et al., alone or in combination with Petschek et al. do not teach or suggest the claimed subject matter, and as such, claim 9 is believed to be allowable. Claim 13 depends from and further defines patentably distinct claim 9 and is also believed allowable.

CONCLUSION

Claims 1-6, 8-14, and 16-19 remain pending in the application. Applicant believes that all of the claims are in condition for allowance and respectfully requests a Notice of Allowance be issued in this case. If the Examiner has any questions regarding this application, please contact the undersigned attorney at (612) 312-2203.

Respectfully submitted,

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Marked-up Version of Claims

(Twice Amended) A computer readable medium for controlling the operation of an 1. automated machine, the computer readable medium comprising machine readable instructions for causing a computer to perform a method comprising:

issuing a command set to initiate a plurality of nucleic acid isolation functions by a nucleic acid isolation apparatus, wherein the nucleic acid isolation functions comprise:

loading a vessel into a centrifuge;

centrifuging a sample;

aspirating a sample [at a selectable aspiration rate from gentle to vigorous];

mixing a sample;

dispensing into a sample;

controlling the temperature of a function;

removing material from a sample;

separating a sample; and

removing and separating a sample;

wherein each of the functions except centrifuging is performed external to a centrifuge.

6. (Amended) A computer system for configuring a machine to automatically perform a method of isolating nucleic acids, the computer system comprising:

a computer;

a computer readable medium comprising machine readable instructions for causing the computer to output a command series to an automated nucleic acid isolation machine for control of the functions of nucleic acids isolation process;

wherein the computer readable medium comprises:

a software module comprising:

a centrifugation sub-module for issuing commands initiating

centrifuging of a sample for a centrifuge time and a centrifuge speed;

an aspiration sub-module for issuing commands initiating aspirating a sample to remove a volume of fluid from a sample;

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a mixing sub-module for issuing commands initiating mixing a sample; a dispensing module for issuing commands initiating dispensing into a sample an amount of a specific reagent;

a temperature control module for issuing commands to control the temperature of a function;

a removal module for issuing commands to remove material from a sample;

a separation module for issuing commands to separate a sample into components; and

a combination removal and separation module for issuing commands to control separating and removing a sample; and wherein each sub-module except the centrifugation sub-module is configured to

control operation external to a centrifuge.

9. (Twice Amended) A control module for controlling the operation of an automated nucleic acids isolation apparatus, the module comprising:

a processor; and

a program module comprising a set of machine readable instructions for issuing commands to the automated nucleic acids isolation apparatus to perform a series of steps, comprising:

centrifuging a sample;

aspirating a sample [at a selectable aspiration rate from gentle to vigorous];

mixing a sample;

adding a reagent to the sample;

controlling the temperature of an isolation function;

removing material from a sample;

separating a sample; and

separating and removing a sample;

wherein each of the steps except centrifuging is performed external to a centrifuge.

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(Amended) A computer control module for an automated nucleic acids isolation 14. apparatus, the control module comprising:

a plurality of sub-modules, each sub-module comprising machine readable instructions for creating a command to the nucleic acids isolation apparatus to perform a process step of the nucleic acids isolation process; and

an output link for communicating the commands to the nucleic acids isolation apparatus;

wherein the plurality of sub-modules comprises:

a centrifuge sub-module for issuing commands initiating centrifuging of a sample for a centrifuge time and a centrifuge speed;

an aspirate sub-module for issuing commands initiating aspirating a sample to remove a volume of fluid from a sample;

a mixing sub-module for issuing commands initiating mixing a sample; a dispensing module for issuing commands initiating dispensing into a sample an amount of a specific reagent;

a temperature control module for issuing commands to control the temperature of a function;

a removal module for issuing commands to remove material from a sample;

a separation module for issuing commands to separate a sample into components; and

a combination removal and separation module for issuing commands to control separating and removing a sample;

wherein each sub-module except the centrifugation sub-module is configured to control operation external to a centrifuge.